

PDBP Inclusion and Exclusion Criteria

Inclusion and Exclusion Criteria are as specified in individual investigator protocols. Listed here are the common inclusion and exclusion criteria.

Instructions: Complete Information as indicated. * **Required fields**

* Name of Site: _____	* Type of Visit: _____ e.g. Screening, Baseline, 6 months, 12 months, 18 months, 24 months, 30 months, 36 months, 42 months, 48 months, 54 months, 60 months.
* Date of Visit: _____	* GUID: _____
Subject ID: _____	

1) Is the subject a control? (If the subject is a control, please answer questions 2, 3 and 7)

☐ Yes ☐ No

2) Please select which of the following inclusion criteria apply to the control:

☐ Male or Female aged 21 years or older at screening

3) Please select which of the following exclusion criteria apply to the control:

- ☐ Unable to participate in consent procedures.
- ☐ Family history of Neurodegenerative disease in a first degree relative or second degree blood relative.
- ☐ Has a current or clinically significant neurological disorder in the opinion of the investigator.
- ☐ Use of investigational drugs or devices within 60 days prior to baseline visit (dietary supplements such as Coenzyme Q10, for example, are not exclusionary).
- ☐ Has a history of schizophrenia.
- ☐ Has a history of neuroleptic use or exposure.
- ☐ Current treatment with anti-coagulants (eg, Coumadin, heparin) that might preclude safe completion of the lumbar puncture.
- ☐ Condition that precludes the safe performance of routine lumbar puncture, such as prohibitive lumbar spinal disease, bleeding diathesis, or coagulopathy or thrombocytopenia.
- ☐ Otherwise unable to participate in biological specimen collection due to a medical condition or medication status (other than items listed above).
- ☐ Otherwise unable to participate in clinical assessments due to a medical condition or medication status (other than items listed above).
- ☐ Otherwise excluded, reason not listed here.

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4) Is the subject a case?

☐ Yes

☐ No

5) Please select which of the following inclusion criteria apply to the case:

- ☐ Male or Female aged 21 years or older at screening
- ☐ Clinically diagnosed with Parkinson's disease (or other Neurodegenerative disease appropriate for study protocol)
- ☐ Able to cooperate with consent procedures (or has appropriate surrogate as defined and approved per local IRB)
- ☐ Able to participate in study activities including all required clinical assessments and biological donations
- ☐ Participation would not lead to hardship or adverse health or mental health conditions

6) Please select which of the following exclusion criteria apply to the case:

- ☐ Unable to participate in consent procedures (or does not have appropriate surrogate per IRB approved protocol for consent).
- ☐ Use of investigational drugs or devices within 60 days prior to baseline visit (dietary supplements such as Coenzyme Q10, for example, are not exclusionary).
- ☐ Clinical Diagnosis uncertain at time of enrollment.
- ☐ Has a history of schizophrenia.
- ☐ Has a history of neuroleptic use or exposure.
- ☐ Current treatment with anti-coagulants (e.g., Coumadin, heparin) that might preclude safe completion of the lumbar puncture.
- ☐ Condition that precludes the safe performance of routine lumbar puncture, such as prohibitive lumbar spinal disease, bleeding diathesis, or coagulopathy or thrombocytopenia.
- ☐ Otherwise unable to participate in biological specimen collection due to a medical condition or medication status (other than items listed above).
- ☐ Otherwise unable to participate in clinical assessments due to a medical condition or medication status (other than items listed above).
- ☐ Otherwise excluded, reason not listed here.

7) Is the subject eligible for study enrollment based on the above criteria (subject meets inclusion criteria and is not excluded for any reason)?

☐ Yes

☐ No

GENERAL INSTRUCTIONS

The study inclusion and exclusion criteria specify the characteristics of potential study participants/subjects that must be met prior to enrollment. Criteria may specify the appropriate age range, symptoms, disease area, etc. Additionally, circumstances that may hamper adherence to the protocol may also be listed in the inclusion and exclusion criteria (e.g., patient has another life-threatening disease or does not understand English.)

All Inclusion Criteria must be answered YES and all Exclusion Criteria must be answered NO or N/A in order for the participant/subject to be considered eligible for study participation.

Data system edit checks may need to be implemented on a study by study basis for situations where participants/subjects do not meet the eligibility criteria, but are still enrolled in the study.

SPECIFIC INSTRUCTIONS

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- **Is the participants/subject eligible for study enrollment based on the above criteria?** - The participants/subject is eligible for study enrollment if all the inclusion criteria are answered YES and all the exclusion criteria are answered NO or N/A.
- **Inclusion Criterion Number(s)** - Enter the number(s) for the inclusion criterion/criteria the participant/subject did not meet. Multiple numbers should be separated by a comma.
- **Exclusion Criterion Number(s)** - Enter the number(s) for the exclusion criterion/criteria the participant/subject did not meet. Multiple numbers should be separated by a comma.